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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,535

06/03/2005

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595552000100

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20872 7590 01/21/2010
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EXAMINER

DANEGA, RENEE A

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

01/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,535	Applicant(s) MCADAMS, ERIC THOMAS	
	Examiner Renee Danega	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31, 34-40, 46-48, 50, 53-56, 59 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31, 34-40, 46-48, 50, 53-56, 59, 62-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 31, 34-36, 39-40 and 46-48, 50, 54-56, 59 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US 6963772) in view of Pearlman and Kenan et al. (US 6788966).

- Regarding claims 31, 34-37, 39-40, 47-48, 50, 54-56, 59, 62, 64 Bloom teaches a system and method for monitoring changes in a skin wound over time comprising a wound dressing (40) including a two dimensional rectangular array of at least 25 test electrodes (38) for application to the surface of the wound (4), circuit means comprising switching device and analyzer for passing an electrical alternating current between each selected test electrode and a further electrode electrically coupled to the test electrodes for measuring an impedance of the tissue underlying each test electrode (78), and a display means (92) capable of presenting a visual map indicating the size and shape of the lesion. Bloom teaches the circuit comprising a first test electrode for providing a current source (4) integrated in the two-dimensional array of test electrodes, a second test

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electrode (10) for completing a current loop with the first electrode, and a third test electrode applied to tissue adjacent the first electrode (38's) (Figures 2D and 4) Bloom doesn't expressly teach presenting a visual map indicating the size and shape of the wound. However, Pearlman teaches a device that employs current through multiple electrodes on hydrogel at the skin surface in order to map a lesion (abstract) (Figures 7B, 14-15) column 9, lines 39-52) (column 4, lines 47-65). It would have been obvious in view of Pearlman to use impedance in order to create an image and display of abnormalities. Pearlman doesn't expressly teach the device to be used for skin lesions. However, Kanan teaches that skin impedance measurements can be used to identify skin lesions. It would have been obvious in view of Kanan to use the system of Bloom to monitor skin lesions and track changes.

- Regarding claim 48, Bloom teaches measuring impedance over a plurality of frequencies but doesn't expressly teach a range. However, Pearlman teaches measuring tissue anomalies by taking impedance measurements over a range of 1mHz to 100 kHz (column 21, lines 14-28). It would have been obvious in view of Pearlman to take impedance measurements in this range in Bloom to detect tissue anomalies.
- Regarding claims 46 and 53, Bloom teaches the test electrodes arranged on a flexible backing of insulating material with the electrodes covered with a conductive gel inherently creating high resistance between the

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electrodes relative to the resistance to the underlying tissue (column 11, lines 5-21).

- Regarding claims 63 and 65, Bloom teaches at least one reference electrode is a dedicated electrode on the flexible backing of insulating material (Figure 2C).

3. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom as applied to claims 31 above, and further in view of Cudahy et al. (US 5184620).

- Regarding claim 38, Bloom teaches the leads (4) to be disposed on the flexible backing of insulating material with the electrodes (38) (Figure 4), but doesn't expressly teach the leads to be covered with an insulating material. However, Cudahy teaches the electrodes to be insulated by the pad from other conductors (column 6, lines 17-20). It would have been obvious in view of Cudahy to provide insulation over the leads in Bloom as well as the electrodes to prevent conductance between the wires.

Response to Arguments

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's arguments filed regarding the use of the Bloom reference have been fully considered but they are not persuasive. Applicant states that the Bloom reference doesn't teach measuring changes in a skin wound; however, the changes in fluid are directly correlated to the surface wound as disclosed as well as sites of inflammation

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(column 6, lines 47-53). Furthermore the reference points to the array to be a plurality of temperature or impedance sensors (column 8, lines 40-45). and claim 31 as written doesn't require the system to create a visual map from the measured electrical characteristics.

6. Kenan teaches a skin lesion impedance measuring system examining tissue at the skin surface and generating a map (column 6, lines 54-62) (column 7, lines 4-25). Therefore, Pearlman's impedance measuring system could be adapted to measure impedance at the surface for mapping rather than beneath it.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736